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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/44 — A1

(11) International Publication Number: **WO 97/26847**

(43) International Publication Date: 31 July 1997 (31.07.97)

(21) International Application Number: PCT/US97/00457

(22) International Filing Date: 17 January 1997 (17.01.97)

(30) Priority Data:
08/590,293 23 January 1996 (23.01.96) US

(60) Parent Application or Grant
(63) Related by Continuation
US
Filed on 08/590,293 (CIP)
23 January 1996 (23.01.96)

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(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: ARTICULATING JOINT REPAIR

(57) Abstract

A method and related materials and apparatus for using minimally invasive means to repair (e.g., reconstruct) tissue such as fibrocartilage, and particularly fibrocartilage associated with diarthroidal and amphiarthroidal joints. The method involves the use of minimally invasive means to access and prepare damaged or diseased fribrocartilage within the body, and to then deliver a curable biomaterial, such as a curable polyurethane system, to the prepared site, and to cure the biomaterial *in situ* in order to repair the fibrocartilage. Applications include repair (e.g., reconstruction or replacement) of the intervertebral disc of the spine. An apparatus is provided in the form of an uninflated balloon that can be inserted into the disc space and there inflated with biomaterial in order to distract the space and provide a permanent replacement disc.

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ARTICULATING JOINT REPAIR

TECHNICAL FIELD

The present invention relates to methods, apparatuses, materials and systems for the repair of movable and mixed articulating joints in the body.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Applications having Serial No. 08/590,293, filed January 23, 1996, which is a continuation-in-part of Serial No. 08/239,248, filed May 6, 1994 for JOINT RESURFACING SYSTEM.

BACKGROUND OF THE INVENTION

The joints of the body can be classified as between those that provide immovable articulations (synarthroidal), mixed articulations (amphiarthroidal), and movable articulations (diarthroidal). The ability of amphiarthroidal and diarthroidal joints to provide effective and pain-free articulation, and/or to serve their weight-bearing function, is generally dependent on the presence of intact, healthy fibrocartilage and/or hyalin cartilage within the joint.

In an amphiarthroidal joint such as the lumbar joint of the back, the vertebra are separated by an intervertebral disc formed of fibrocartilage. More particularly, the intervertebral disc is comprised of an outer annulus fibrosis formed of fibrocartilage. The annulus, in turn, surrounds and contains a more fluid material known as the nucleus pulposus. By virtue of its fluidity, the nucleus allows for both movement and weight-bearing energy transfer. In healthy, generally younger individuals, the annulus is intact and the nucleus pulposus remains quite fluid.

As people age, however, the annulus tends to thicken, desiccate, and become more rigid. The nucleus pulposus, in turn, becomes more viscous and

less fluid and sometimes even dehydrates and contracts. The annulus also becomes susceptible to fracturing or fissuring. These fractures tend to occur all around the circumference of the annulus, and can extend from both the outside of the annulus inward, and from the interior outward. Occasionally, a fissure from the outside will meet a fissure from the inside and will result in a complete rent through the annulus fibrosis. In a situation like this, the nucleus pulposus may extrude out through the intervertebral disc. The extruded material, in turn, can impinge on the spinal cord or on the spinal nerve rootlets as they exit through the intervertebral foramen, resulting in the symptoms associated with the classic "ruptured disc".

The current surgical approach to treating a degenerated intervertebral disc generally involves the process of microdiscectomy, in which the site is accessed and the protruded material is removed. This often produces significant relief, provided it is a fairly minor, or mild, localized disc protrusion. In such a procedure a small incision is made, through which the disc is visualized. The area of protruded material is removed, thus decompressing the nerve rootlet that has been impinged on by the extruded material.

In more severe situations, however, the annulus fibrosis becomes degenerated to the point where very little disc space remains, and much of the nucleus pulposus is either contracted or has been extruded. Regional osteophytes can also develop around these areas. The combination of the extruded material and the osteophytes, together with the narrowing of the intervertebral disc space produces a marked narrowing of the intervertebral foramen and impingement on the spinal nerve rootlet as it exits the canal. This is the classical situation that results in radicular pain with axial loading.

When this occurs it becomes necessary to reestablish the intervertebral space. The current approach to this more severe situation is a lumbar laminectomy (to decompress the nerve rootlet) with fusion of the disc space. The bony lamina is removed to decompress the intervertebral foramina and the bone graft is taken from the anterior iliac crest and attached from one vertebrae body to

the next. The resulting fusion will maintain stability at that point and also help maintain the separation of the vertebrae.

Recent advances in this technology have been developed by such companies as Spine-Tech, Minneapolis, MN, which involves the use of a titanium alloy cylinder. The cylinder is screwed into the intervertebral space to assure the stability of the spacing until a fully bony ankylosis can be obtained. The cylinders are packed with bone and are fenestrated so that the packed bone can grow out into the adjacent vertebrae and solidify the fusion. To date, however, clinical results on the long-term follow up of these patients are not available and the efficacy is still in doubt with many spine surgeons.

It would therefore be particularly useful to be able to repair such injuries in a manner that avoids invasive surgical procedures and the problems associated therewith.

SUMMARY OF THE INVENTION

The present invention provides a method and related materials and apparatus for using minimally invasive means to repair (e.g., reconstruct) tissue such as fibrocartilage, and particularly fibrocartilage associated with diarthroidal and amphiarthroidal joints. The method involves the use of minimally invasive means to access and prepare damaged or diseased fibrocartilage within the body, and to then deliver a curable biomaterial to the prepared site, and to cure the biomaterial *in situ* in order to repair the fibrocartilage and replace the function of the damaged cartilage. The biomaterial provides an optimal combination of such properties as deliverability and curability, as well as biocompatability, biostability, and such physical performance characteristics as strength, elasticity, and lubricity.

In one embodiment, the method comprises the steps of:

a) using minimally invasive means to remove damaged or diseased fibrocartilage from a diarthroidal or amphiarthroidal joint, and to create a mold capable of containing curable biomaterial in a desired position within the joint,

b) providing one or more curable biomaterials to the structure previously occupied by the removed fibrocartilage, and

c) curing the biomaterials in order to provide a replacement for the fibrocartilage.

The mold created within the joint is preferably of sufficient shape and dimensions to allow the resulting cured biomaterial to replace or mimic the structure and function of the removed fibrocartilage. The mold can be formed of synthetic and/or natural materials, including those that are provided exogenously and those provided by the remaining natural tissues. The mold can either be removed from the site, upon curing of the biomaterial, or is sufficiently biocompatible to allow it to remain in position.

The mold can take the form of either a positive and/or negative mold. For instance, the mold can take the form of an outer shell, capable of retaining biomaterial within its interior cavity. Optionally, the mold can also take any other suitable form, including to serve as an interior core (e.g., to create a doughnut shaped biomaterial), or as an anchor point for the stable attachment and localization of delivered biomaterial.

In a particularly preferred embodiment, the method is used to repair an amphiarthroidal joint such as an intervertebral disc and comprises the steps of:

a) using microsurgical techniques to perform a discectomy while preserving an outer annular shell,

b) providing one or more curable biomaterials to the interior of the annular shell, and

c) curing the biomaterials in order to provide a replacement disc.

In such a preferred embodiment, the distraction of the disc space is accomplished by means of a suitable distraction means, such as an inflatable, yet rigid, balloon or bladder. The balloon can be delivered in deflated form to the interior of the annulus and there inflated in order to distract the disc space and provide a region for the delivery of biomaterial. The balloon is preferably of

sufficient strength and suitable dimensions to distract the space to a desired extent and for a period long enough for the biomaterial to be delivered and cured.

In a preferred embodiment, the invention provides a distraction device comprising an insertable, deflated balloon formed of a self-venting, biocompatible material capable of retaining polymer and distracting a joint space at up to about 10 atmosphere pressure.

In other aspects, the invention provides biomaterials, including polymer systems, useful for performing such a method, as well as methods of preparing and using such biomaterials. In yet further aspects, the invention provides a diarthroidal or amphiarthroidal joint having interposed therein a biomaterial that has been cured *in situ*.

DETAILED DESCRIPTION

Applicants have discovered a means for producing spinal separation to achieve pain relief, which involves the step of interposing cured biomaterial in the intervertebral disc space.

Definitions

As used herein the following words and terms shall have the meanings ascribed below:

"repair" will refer to the use of a biomaterial to replace or provide some or all of the structure or function of natural tissue *in vivo*, for instance, to repair (e.g., reconstruct or replace) cartilage, such as fibrocartilage, present in a diarthroidal or amphiarthroidal joint. Repair can take any suitable form, e.g., from patching the tissue to replacing it in its entirety, preferably in a manner that reconstructs its native dimensions;

"biomaterial" will refer to a material that is capable of being introduced to the site of a joint by minimally invasive means, and be cured to provide desired physical-chemical properties *in vivo*;

"cure" and inflections thereof, will refer to any chemical-physical transformation that allows a biomaterial to progress from a form (e.g., flowable

form) that allows it to be delivered by minimally invasive means, to a more permanent form for final use *in vivo*. When used with regard to the method of the invention, for instance, "curable" can refer to uncured biomaterial, having the potential to be cured *in vivo* (as by the application of a suitable energy source), as well as to a biomaterial that is in the process of curing, as with a biomaterial formed at the time of delivery by the concurrent mixing of a plurality of biomaterial components;

"minimally invasive means" refers to surgical means, such as microsurgical or endoscopic or arthroscopic surgical means, that can be accomplished with minimal disruption of the pertinent musculature, for instance, without the need for open access to the tissue injury site or through minimal incisions (e.g., incisions of less than about 4 cm and preferably less than about 2 cm). Such surgical means are typically accomplished by the use of visualization such as fiberoptic or microscopic visualization, and provide a post-operative recovery time that is substantially less than the recovery time that accompanies the corresponding open surgical approach;

"endoscopic/arthroscopic surgical instrument" refers to the controllers and associated hardware and software necessary for performing conventional endoscopic or arthroscopic surgery; and

"delivery cannula" shall mean a cannula capable of being operated in a minimally invasive fashion, e.g., under arthroscopic visualization, together with associated connective tubing and containers for the operable and fluid attachment of the cannula to a source of biomaterial for the storage, delivery, and recovery of biomaterials of the present invention.

Method

In a preferred embodiment, the present invention provides a method and related materials and apparatus for repairing diarthroidal and amphiarthroidal joints by minimally invasive means. The method involves the use of minimally invasive means to prepare the site of injury, deliver a curable biomaterial to the joint site, and to cure the biomaterial *in situ* in order to repair fibrocartilage.

The method of the invention can be used to repair a number of tissues, including a variety of joints, and is particularly useful for diarthroidal and amphiarthroidal joints. Examples of suitable amphiarthroidal joints include the synphysoidal joints, such as the joints between bodies of the vertebrae. Such joints provide surfaces connected by fibrocartilage, and have limited motion. Other examples include syndesmoidal joints, having surfaces united by an interosseous ligament, as in the inferior tibio-fibular joint.

Examples of suitable diarthroidal joints include the ginglymus (a hinge joint, as in the interphalangeal joints and the joint between the humerus and the ulna); throchoides (a pivot joint, as in superior radio-ulnar articulation and atlanto-axial joint); condyloid (ovoid head with elliptical cavity, as in the wrist joint); reciprocal reception (saddle joint formed of convex and concave surfaces, as in the carpo-metacarpal joint of the thumb); enarthrosis (ball and socket joint, as in the hip and shoulder joints) and arthrodia (gliding joint, as in the carpal and tarsal articulations).

In a particularly preferred embodiment, the method is used to repair an amphiarthroidal joint such as an intervertebral disc and comprises the steps of:

a) using microsurgical techniques to perform a discectomy while preserving an outer annular shell,

b) providing a curable biomaterial to the annular shell, and

c) curing the polymer in order to provide a replacement disc.

As can be seen, the annular shell can itself serve as a suitable mold for the delivery and curing of biomaterial. Optionally, the interior surface of the annular shell can be treated or covered with a suitable material in order to enhance its integrity and use as a mold. Preferably, one or more inflatable devices, such as the balloons described herein, can be used to provide molds for the delivery of biomaterials. More preferably, the same inflatable devices used to distract the joint space can further function as molds for the delivery and curing of biomaterial.

Discectomy

A discectomy (i.e., removal of some or all of the nucleus pulposis, leaving an outer annular shell) is performed, with optional distraction and repair of the annulus, in order to remove the destroyed nucleus material while providing an intact annular shell. By "intact", it is meant that the annulus, either alone or with optional supporting means, is of sufficient strength and integrity to retain a biomaterial in a desired position and in the course of its use (delivery and curing).

The microsurgery for the polymeric intervertebral disc replacement can be carried out using techniques well within the skill of those in the art, given the present teaching. The annulus can be viewed, for instance, remote visualization techniques such as fiberoptic visualization. The integrity of the annular shell is assessed, and optionally, the shell itself is repaired, e.g., by the application of a biocompatible patching material, such as a fibrin glue.

The destroyed disc material is cleaned out and the annulus is cleaned out to the edges of the annulus. The annular shell, including any repaired portions are preferably of sufficient strength and dimensions to allow the biomaterial to be delivered and cured. The remaining, repaired annulus then serves as an outer barrier for the curable biomaterial, thereby serving to provide accurate dimensions and location for the cured biomaterial.

Once the nucleus pulposis has been removed and the remaining annulus repaired, the annular shell can itself be used as an envelope to contain the delivered biomaterial. Optionally, and preferably, means are provided to contain the biomaterial within the desired space, e.g., by forming an additional envelope within the annulus.

As used herein the word "distraction", and inflections thereof, will refer to the separation of joint surfaces to a desired extent, without rupture of their binding ligaments and without displacement. Distraction can be accomplished by any suitable means. Such means include mechanical means and hydrostatic means, e.g., by pressurized injection of the biomaterial itself. By the use of distraction, the disc space can be sufficiently re-established to achieve any desired final

dimensions and position. Optionally, and preferably, the means used to accomplish distraction also serve the purpose of forming one or more barriers (e.g., envelopes) for the uncured biomaterial itself.

The disc space can be distracted prior to and/or during either the discectomy itself and/or delivery of biomaterial. A constricted disc space is generally on the order of 3 to 4 mm in the distance between vertebral plates. Suitable distraction means are capable of providing on the order of about 3 atmospheres to about 4 atmospheres, (or on the order of about 40 psi to about 60 psi) in order to distract that space to on the order of 8 to 12 mm between the vertebral plates.

Distraction can be accomplished by any suitable means, including by mechanical and/or hydrostatic means. Mechanical means can include, for instance, attaching hooks or jacks to the bony endplates and using those hooks or jacks to separate the bones. Optionally, the surgeon can employ external traction, however, with the patient on their side, external traction will likely not be preferred.

Optionally, and preferably, the space is distracted by the use of one or more suitable insertable devices, e.g., in the form of inflatable balloons. When inflated, such balloons provide rigid walls (e.g., fiber supported) that are sufficiently strong to distract the space. An inflatable device provides sufficient strength and dimensions can be prepared using conventional materials. In use, the uninflated balloon can be delivered to the center of the annular shell, and there inflated to expand the annular shell and in turn, distract the space.

The inflatable device can be delivered to the disc space by any suitable means, e.g., in deflated form retained within or upon the end of a rigid or semi-rigid rod. Once positioned within the disc, generally centrally within the annular shell, a suitable gas (e.g., nitrogen or carbon dioxide) can be delivered through the rod in order to inflate the balloon *in situ*, in a substantially radial direction. The fact that the balloon is properly placed can be confirmed by the use of

ancillary means, such as cine using a C arm, or by self-effecting means embodied within the balloon itself or its delivery apparatus.

Suitable materials for preparing balloons of the present invention are those that are presently used for such purposes as balloon angioplasty. Suitable materials provide an optimal combination of such properties as compliance, biostability and biocompatability, and mechanical characteristics such as elasticity and strength. Balloons can be provided in any suitable form, including those having a plurality of layers and those having a plurality of compartments when expanded. A useful balloon apparatus will include the balloon itself, together with a delivery catheter (optionally having a plurality of lumen extending longitudinally therewith), and fluid or gas pressure means.

Examples of suitable materials (e.g., resins) for making balloons include, but are not limited to, polyolefin copolymers, polyethylene, polycarbonate, and polyethylene terephthalate. Such polymeric materials can be used in either unsupported form, or in supported form, e.g., by the integration of dacron or other fibers.

Balloons can also take several forms, depending on the manner in which the biomaterial is to be delivered and cured. A single, thin walled balloon can be used, for instance, to contact and form a barrier along the interior surface of the remaining annular material. Once positioned, one or more curable biomaterials can be delivered and cured within the balloon to serve as a replacement for the removed material. In such an embodiment, the balloon is preferably of a type that will allow it to remain in position, without undue detrimental effect, between the annular material and the cured biomaterial.

Optionally, a balloon can be provided that fills less than the entire volume of the annular shell. In such an embodiment, the balloon can be, for instance, in the shape of a cylinder. Such a balloon can be provided such that its ends can be positioned to contact the opposing vertebral bodies, and its walls will provide sufficient strength to cause distraction of the space upon inflation.

Thereafter, a first biomaterial is delivered to perimeter of the annular space, i.e., the space between the annular material and the balloon, and there cured. The biomaterial is delivered using suitable means, and under conditions suitable to ensure that it will not extrude through tears in the annulus. Optionally, the balloon can be gradually deflated as additional biomaterial is inserted into the space.

With the outer biomaterial cured in place, the balloon can be removed and an additional biomaterial, of either the same or a different type, can be delivered and cured in whatever remaining space was previously occupied by the balloon. A second cannula can be used to deliver a second biomaterial, preferably one that cures to provide a more flexible region that more closely approximates the physical characteristics of the original nucleus. This method provides the option to reconstruct the disc in a manner that more closely approximates the overall physical characteristics and relationship of the original annulus and nucleus.

A two step approach, as described above, is preferred for a number of reasons. It provides the means for distracting the joint, while at the same time facilitating the preparation of a final reconstructed annulus having two or more regions. The different regions, i.e., a rigid outer shell in combination with a more liquid interior, can provide a function that mimics that of the native disc. In addition to a two step approach, however, an implant having a plurality of regions, can be provided by other means as well. For instance, such an implant can be provided by the delivery of a single biomaterial that is cured to a greater or differing extent in its outermost, as compared to innermost, regions. An implant having a plurality of regions, or even a continuum of properties, is particularly preferred.

In an optional and preferred embodiment, as described above, a balloon can be inserted in uninflated form by means of a delivery catheter, e.g., in the form of a shaft, into the disc space. The balloon can be properly positioned in the disc space, e.g., within the annular shell following discectomy, and inflated upon filling with biomaterial in order to expand the balloon and thereby distract the

space. In such an embodiment, the balloon can be inserted into the space, e.g., in uninflated or partially inflated form, and filled in whole or in part with biomaterial under sufficient conditions, including pressure, to distract the space. Concurrently, the biomaterial can be fully cured in the course of filling the balloon, in order to be retained permanently in position within the balloon and the distracted space.

A preferred balloon configuration includes an uninflated balloon attached to a shaft, both of which are optionally provided in a initial form covered by a removable sleeve portion, the assembled device being useful as an applicator to deliver the balloon in uninflated form to the disc space. A suitable balloon attachment site is provided in the form of an integral balloon stem portion, which can be retained in sealed but severable contact with the distal end of the shaft.

A suitable sleeve portion is provided in the form of coaxial, telescoping sleeve having both a narrowed region dimensioned to cover the shaft itself, and an expanded region capable of retaining the balloon in a rolled or folded configuration in the course of delivering the balloon to the site. Thereafter, as the sleeve is removed, the expanded pocket is pulled back to release the balloon in situ. The sleeve can be fabricated from suitable materials and using techniques within the skill of those in the art, given the present description. Optionally, any portion, region or surface of the sleeve, shaft or balloon can be treated with friction reducing coatings or other materials to improve or otherwise alter the lubricity or other physical or chemical properties.

A balloon of the present invention can be inflatably attached (e.g., provided in an releasable and uninflated configuration) within or upon the end of a delivery shaft, in order to be inserted into the disc space. Preferably, the shaft and balloon are of sufficient dimensions and properties to permit the balloon to be inserted using minimally invasive means, including fiberoptic visualization.

The shaft is preferably provided in the form of an elongated tube having a distal end capable of being inserted to the disc space by minimally invasive means, and a proximal end providing an attachment site for a source of biomaterial. The

shaft is sufficiently stiff and flexible to permit it to be inserted into a tissue access site of on the order of 4 cm or less, and preferably on the order of 2 cm or less, and moved through the body to access the disc site, while also having sufficient dimensions and surface properties to permit the flow of a desired biomaterial into the attached balloon.

Once in place within the disc space, the balloon can be finally positioned within the space and filled with biomaterial, flowing through the shaft, and under sufficient pressure to distract the space. In a preferred embodiment, the balloon is "self-venting", in that whatever volume of gas may be present within the balloon and shaft at the time of insertion can be displaced by the biomaterial and vented through the balloon walls, e.g., to the surrounding tissue. Optionally, or additionally, the shaft and/or balloon can be evacuated by the application of suction or vacuum to the shaft.

Preferably, some or all of the gas (e.g., air) present within the shaft and/or balloon is vented through the balloon material by virtue, and in the course, of the delivery of biomaterial. As the biomaterial fills the balloon, and displaces the gas, the biomaterial also serves to inflate the balloon to a desired extent, and in a suitable position to distract the disc space. Once the disc space has been sufficiently distracted, the biomaterial can be cured, or permitted to fully cure, in situ in order to retain the balloon and biomaterial permanently in place.

A preferred distraction device of this type comprises an insertable, uninflated balloon formed of a self-venting, biocompatible material capable of retaining a biomaterial in the course of joint distraction. Such a device, for instance, is capable of distracting a joint space by providing up to about 5 atmospheres or more distraction pressure, and preferably up to about 10 atmospheres or more. Preferably, the balloon itself is capable of withstanding substantially greater pressure than that required to distract the space, e.g., up to about 10 atmospheres and preferably up to about 15 atmospheres or more.

In a particularly preferred embodiment, the balloon is fabricated from natural or synthetic materials, including but not limited to, polymeric materials,

such as films or membranes, and woven or nonwoven fabrics or meshes, having properties sufficient to permit gasses to be vented through the material in situ in the course of delivering the biomaterial. The balloon can be fabricated as one or more layers comprising such materials, and/or with one or more regions or portions of differing properties.

Those skilled in the pertinent art, given the present teaching, will appreciate the manner in which preferred balloons, including the materials used to fabricate balloons, will provide an optimal combination of such properties as biocompatability, biodurability, strength, wall thickness, wettability with a biomaterial, gas permeability (e.g., gas venting ability), puncture resistance, compliance, flexibility, modulus of elasticity, stress/strain curve yield point, burst pressure, maximum inflation, and the ability to be easily fabricated and sterilized.

Examples of suitable balloon materials include, but are not limited to, solid polymeric materials such as membranes. Such polymeric materials can be provided with suitable venting holes, e.g., produced by the use of excimer laser.

Preferred materials include fabrics and meshes that are preferably also wettable by the biomaterial of choice, in order to allow the biomaterial to seep through the mesh as it cures, and to bond with and/or around the threads of the mesh in order to form an integral structure with the mesh. In a presently preferred embodiment the resulting surface of the filled, cured balloon is generally uniform, having portions of the fabric scrim exposed. Optionally, the material used to fabricate the balloon can itself be provided (e.g., impregnated or coated) with suitable modifiers capable of affecting the rate and/or degree of biomaterial cure. The use of a suitable catalyst, for instance, can serve to cure the biomaterial more quickly upon contact with the material, thereby providing an outermost region having different chemical properties in the fully cured implant.

Suitable polymeric materials include elastomeric and other materials commonly used for angioplasty and related applications, and include polyurethanes, polyolefins, polyamides, polyvinyl chlorides, and polyethylene

terephthalates, as well as various copolymers, combinations and permutations thereof.

Preferred balloon materials are available commercially for use in filtration and other applications, and include clothes and meshes formed of polymeric materials such as polyester, polypropylene and nylon threads. Optionally, a material can be reinforced, e.g., with woven glass or fine fibers of other materials, to provided added strength or other desirable properties. Such materials are selected to provide an optimal combination of such properties as strength, mesh opening, thread diameter, mesh count, percent open area, and cost.

Suitable materials, for instance, provide a mesh opening of between about 1 and about 100 microns and preferably between about 1 and about 10 microns. Suitable materials further provide a thread diameter of between about 20 microns and about 50 microns, and a percent open area of between about 1% and about 5%. Examples of particularly preferred materials are commercially available and include, but are not limited to, nylon screen cloth, such as a nylon mesh available as Part No E-CMN-5 (5 micron mesh opening) from Small Parts, Inc. Miami Lakes, Fl, and from Tetko Inc.

Suitable materials for fabricating the shaft portion of a distraction device include polymeric materials that are preferably chemically compatible with the balloon (in order to facilitate attachment of the two), sufficiently strong (to withstand the biomaterial delivery pressure), and sufficiently flexible and inert in order to facilitate their use in vivo while positioning the balloon. A shaft can be of any desired dimensions, e.g., on the order of 5 to 10 cm in height, 2 to 5 mm, and preferably 3 to 4 mm external diameter, and 1mm to 4mm, and preferably 2mm to 3 mm inner diameter, with wall thickness of on the order of 0.3 mm to 1 mm.

The balloons themselves can be fabricated by a variety of means. In one preferred embodiment, the balloon is formed as a continuous (e.g., unitary) and non-interrupted (e.g., seamless) form, and optionally, as an integral part of the distal end of the delivery shaft. A membrane material can be formed, for

instance, by positioning it over a suitably shaped mandrel under suitable conditions of time and temperature in order to cause the membrane to permanently conform to the shape of the mandrel.

In another preferred embodiment, the balloon is fabricated from a plurality of generally sheet-like portions, which can be assembled and sealed together. Sealing can be accomplished by any suitable means, including by the use of adhesives, sewing, RF bonding, heat sealing, impulse sealing, and any combination thereof. A particularly preferred seal is provided by RF bonding following by a bead of a compatible adhesive capable of saturating the bond. Once sealed, the balloon is preferably turned inside out in order to provide the sealed seam on the interior of the resultant balloon.

The balloon can be fabricated to assume any desired shape upon inflation, and in a preferred embodiment is provided in a generally ovoid shape, and preferably in the approximate shape of a kidney bean, in order to approximate the natural anatomical shape of the disc space itself. Preferably, the balloon provides two major surfaces for contacting respective vertebral end plates facing the disc space. The balloon further provides wall portions for contact with the annular shell within the disc space.

The dimensions of the balloon will typically vary according to their intended use. For use in the lumbar region of an adult male, for instance, the inflated balloon will typically have a lateral dimension of between about 20 mm and about 40 mm, and preferably between about 25 mm and about 35 mm, as well as an anterior/posterior dimension of between about 15 mm and about 25 mm, and will inflate to between about 10 mm and about 15 mm in height for use in distracting the space. For the cervical region and thoracic region these dimensions will be approximately one-half, and three-fourths, respectively of the lumbar dimensions.

When provided as a separate component attached to a delivery shaft, the balloon will preferably also include an integral stem or cuff portion or a region

having a reduced diameter (e.g., on the order of 5 mm to 10 mm) for use in attaching the balloon to the distal end of the shaft.

A suitable mechanical attachment for securing the balloon to the shaft involves tightly wrapping the end of the balloon with a fine thread or suture to provide a seal between the balloon and shaft. The balloon can be attached other means as well, e.g., by gluing, attaching, or integrally forming the balloon and/or a stem attached to the balloon to the cannula end. Optionally, the balloon is attached to the shaft by means of an integral stem, which preferably provides a region that extends from the shaft and is unsealed, in order to provide a useful site for separating (e.g., cutting) the balloon from the shaft.

Preferably the distraction device (e.g., either the balloon and/or the shaft portion) is provided with one or more orientation markers, in order to permit the surgeon to determine the optimal orientation of the balloon in situ. Suitable orientation markers include, but are not limited to, the placement of detectable markers or indications within or upon the balloon material and/or catheter, the markings or indications themselves being detectable by minimally invasive means, e.g., by fiberoptic visualization, interoperative magnetic resonance imaging (MRI), ultrasound, and laser radiation. The position of the shaft attachment to the balloon can itself be designed so as to permit the surgeon to properly place the balloon in the desired location in the course of surgery.

The uninflated balloon is preferably positioned within the annular shell, following discectomy. As described above, mechanical distraction of the space can be used as well, e.g., either while inserting and/or positioning the balloon and/or during inflation of the balloon with biomaterial. A suitable mechanical distraction device for this purpose includes the use of a plurality of pins (e.g., screws) that can be placed in the opposing vertebrae and grasped with a matable instrument, e.g., having a scissors-like grip and movement.

Once in place within the disc the balloon can be filled by having the shaft connected to a biomaterial delivery device capable of delivering biomaterial

through the shaft and into the balloon under sufficient pressure, optionally with mechanical distraction, to expand the balloon and distract the space. When in the form of a two-part curable polyurethane as described herein, the biomaterial will begin to cure as it leaves the mixing chamber of the delivery device. It will continue to cure as it progresses through the shaft and into the balloon. Ideally, the cure rate of the biopolymer is controlled, in combination with the dimensions and other conditions of the distraction device, in order to provide sufficient time for the biomaterial to expand the balloon before final curing occurs. The distraction progress can be monitored, e.g., by C arm cine or interoperative MRI.

Finally, the shaft can be removed from the inserted, inflated and cured balloon/biomaterial combination by any suitable means, e.g., by cutting the stem of the balloon using surgical means, or by heating a wire that has been previously embedded in or around the circumference of the balloon stem.

Biomaterials

Natural cartilage is a non-vascular structure found in various parts of the body. Articular cartilage tends to exist as a finely granular matrix forming a thin incrustation on the surfaces of joints. The natural elasticity of articular cartilage enables it to break the force of concussions, while its smoothness affords ease and freedom of movement. Preferred biomaterials, therefore, are intended to mimic many of the physical-chemical characteristics of natural cartilage. Biomaterials can be provided as one component systems, or as two or more component systems that can be mixed prior to or during delivery, or at the site of repair. Generally such biomaterials are flowable in their uncured form, meaning they are of sufficient viscosity to allow their delivery through a cannula of on the order of about 2 mm to about 6 mm inner diameter, and preferably of about 3 mm to about 5 mm inner diameter. Such biomaterials are also curable, meaning that they can be cured or otherwise modified, *in situ*, at the tissue site, in order to undergo a phase or chemical change sufficient to retain a desired position and configuration.

When cured, preferred materials can be homogeneous (i.e., providing the same chemical-physical parameters throughout), or they can be heterogeneous. An

example of a heterogeneous biomaterial for use as a disc replacement is a biomaterial that mimics the natural disc by providing a more rigid outer envelope (akin to the annulus) and an more liquid interior core (akin to the nucleus). In an alternative embodiment, biomaterials can be used that provide implants having varying regions of varying or different physical-chemical properties. With disc replacement, for instance, biomaterials can be used to provide a more rigid, annulus-like outer region, and a more fluid, nucleus-like core. Such di-or higher phasic cured materials can be prepared by the use of a single biomaterial, e.g., one that undergoes varying states of cure, or a plurality of biomaterials.

Common polymeric materials for use in medical devices include, for example, polyvinyl chlorides, polyethylenes, styrenic resins, polypropylene, thermoplastic polyesters, thermoplastic elastomers, polycarbonates, acrylonitrile-butadiene-styrene ("ABS") resins, acrylics, polyurethanes, nylons, styrene acrylonitriles, and cellulosics. See, for example, "Guide to Medical Plastics", pages 41-78 in Medical Device & Diagnostic Industry, April, 1994, the disclosure of which is incorporated herein by reference.

Suitable biomaterials for use in the present invention are those polymeric materials that provide an optimal combination of properties relating to their manufacture, application, and *in vivo* use. In the uncured state, such properties include processability, and the ability to be stably sterilized and stored. In the course of applying such material, such properties as flowability, moldability, and *in vivo* curability. In the cured state, such properties include cured strength (e.g., tensile and compressive), stiffness, biocompatability and biostability. Examples of suitable biomaterials include, but are not limited to, polyurethane polymers.

In a preferred embodiment, the biomaterial comprises a polyurethane polymer. Polyurethanes, e.g, thermoplastic polyurethanes ("TPU"), are typically prepared using three reactants: an isocyanate, a long-chain macrodiol, and a short-chain diol extender. The isocyanate and long-chain diol form a "soft" segment, while the isocyanate and short-chain diol form a "hard" segment. The hard segments form ordered domains held together by hydrogen bonding. These

domains act as cross-links to the linear chains, making the material similar to a cross-linked rubber. It is the interaction of soft and hard segments that determines and provides the polymer with rubber-like properties.

Those skilled in the art, in view of the present invention, will appreciate the manner in which the choice of isocyanate, macrodiol, and chain extender can be varied to achieve a wide array of properties. Preferred TPU's for medical use are presently based on the use of a diisocyanate such as diphenylmethane diisocyanate ("MDI"), a glycol such as polytetramethylene ether glycol, and a diol such as 1,4-butanediol.

In an further preferred embodiment, the biomaterial comprises a thermosetting polyurethane polymer based on a suitable combination of isocyanates, long chain polyols and short chain (low molecular weight) extenders and/or crosslinkers. Suitable components are commercially available and are each preferably used in the highest possible grade, e.g., reagent or preferably analytical grade or higher. Examples of suitable isocyanates include 4,4'-diphenyl methane diisocyanate ("MDI"), and 4,2'-diphenylmethane diisocyante, including mixtures thereof, as well as toluene diisocyanate ("TDI"). Examples of suitable long chain polyols include tetrahydrofuran polymers such as poly(tetramethylene oxide) ("PTMO"). Particularly preferred are combinations of PTMO's having molecular weights of 250 and 1000, in ratios of between about 1 to 1 and about 1 to 3 parts, respectively. Examples of suitable extenders/crosslinkers include 1,4-butanediol and trimethylol propane, and blends thereof, preferably used at a ratio of between about 1 to 1 and about 1 to 7 parts, respectively.

Biomaterials of the present invention can also include other optional adjuvants and additives, such as stabilizers, fillers, antioxidants, catalysts, plasticizers, pigments, and lubricants, to the extent such optional ingredients do not diminish the utility of the composition for its intended purpose.

When cured, the biomaterials demonstrate an optimal combination of physical/chemical properties, particularly in terms of their conformational stability,

dissolution stability, biocompatability, and physical performance, e.g., physical properties such as density, thickness, and surface roughness, and mechanical properties such as load-bearing strength, tensile strength, shear strength, fatigue, impact absorption, wear characteristics, and surface abrasion. Such performance can be evaluated using procedures commonly accepted for the evaluation of natural tissue and joints, as well as the evaluation of biomaterials.

In particular, preferred biomaterials, in the cured form, exhibit mechanical properties that approximate those of the natural tissue that they are intended to replace. For instance, for load bearing applications, preferred cured composites exhibit a load bearing strength of between about 50 and about 200 psi (pounds per square inch), and preferably between about 100 and about 150 psi. Such composites also exhibit a shear stress of between about 10 and 100 psi, and preferably between about 30 and 50 psi, as such units are typically determined in the evaluation of natural tissue and joints.

Preferred biomaterials are also stable under conditions used for sterilization, and additionally are stable on storage and in the course of delivery. They are also capable of flowing through a delivery cannula to an *in vivo* location, and being cured *in situ*, as by exposure to an energy source such as ultraviolet light or by chemical reaction. Thereafter the cured biomaterial is suitably amenable to shaping and contouring, by the use of conventional or custom designed arthroscopic tools or instruments. Over the course of their use in the body the cured, contoured biomaterial exhibits physical-chemical properties suitable for use in extended *in vivo* applications.

In a preferred embodiment, the biomaterial is a polyurethane provided as a two-part prepolymer system comprising a hydrogenated MDI isocyanate, polyethylene/polypropylene oxide polyol, and 1,4-butanediol as a chain extender. The final polymer having a hard segment content of about 30 to about 40% by weight, based on the weight of the hard segment. Thixotropic agents, such as that available under the tradename "Cab-o-sil TS-720" from Cabot can be, and

preferably are, used to achieve the desired flow and pre-cure viscosity characteristics.

Optionally, and preferably, one or more catalysts are incorporated into one or more components of the biomaterial, in order to cure the biomaterial in the physiological environment within a desired length of time. Preferably, biomaterials of the present invention are able to cure (i.e., to the point where distraction means can be removed and/or other biomaterial added), within on the order of 5 minutes or less, and more preferably within on the order of 3 minutes or less.

Preferably, means are employed to improve the biostability, i.e., the oxidative and/or hydrolytic stability, of the biomaterial *in vivo*, thereby extending the life of the implant. See, for instance, A. Takahara, et al., "Effect of Soft Segment Chemistry on the Biostability of Segmented Polyurethanes. I. In vitro Oxidation", J. Biomedical Materials Research, 25:341-356 (1991) and A. Takahara, et al., "Effect of Soft Segment Chemistry on the Biostability of Segmented Polyurethanes. II. In vitro Hydrolytic Degradation and Lipid Sorption", J. Biomedical Materials Research, 26:801-818 (1992), the disclosures of both of which are incorporated herein by reference.

Suitable means for improving biostability include the use of an aliphatic macrodiol such as hydrogenated polybutadiene (HPDI). By judicious choice of the corresponding diisocyanate (e.g., MDI) and chain extender (e.g., ethylenediamine), those skilled in the art will be able to achieve the desired packing density, or crystallinity, of the hard segments, thereby improving the hydrolytic stability of the cured polyurethane.

Biomaterials provided as a plurality of components, e.g., a two-part polyurethane system, can be mixed at the time of use using suitable mixing techniques, such as those commonly used for the delivery of two-part adhesive formulations. A suitable mixing device involves, for instance, a static mixer having a hollow tube having a segmented, helical vein running through its lumen.

A two-part polyurethane system can be mixed by forcing the respective components through the lumen, under pressure.

In a further embodiment, the static mixer can be used in a system having an application cannula, an application tip, and a cartridge having two or more chambers, each containing a separate component of the biomaterial system. A hand-powered or electrically controlled extrusion gun can be used to extrude the components through the static mixer, in order to completely mix them and thereby begin the process of curing. The biomaterial system then flows through the cannula and to the joint site or surface through the application tip. The length, diameter, and vein design of the mixing element can be varied as necessary to achieve the desired mixing efficiency.

Example

In performing a preferred method of the present invention, the patient is brought to the pre-surgical area and prepped. Anesthesia is then induced and the area of the spine is further prepped. A small incision along the paraspinal muscles is opened under dissecting microscopic visualization. The incision typically ranges between 3 and 6 centimeters in length and is longitudinal in the plane of the spine. The paravertebral muscles are separated by blunt dissection and held apart with forceps and dividers. The intervertebral disc area is visualized, with initial exposure down to the lamina. The area below the lamina, at the point of the intervertebral foramina, can also be exposed.

The disc is examined for extruded material and any extruded material is removed. Magnetic resonance imaging ("MRI") data can be used to determine the integrity of the annulus fibrosis at this point. An arthroscope is inserted into the disc and used to examine the inside of the annulus. Optionally, an intraoperative discogram can be performed, in which a dye material is inserted and visualized in order to substantiate the integrity of the annulus fibrosis. Points of weakness, or rents, in the annulus fibrosis are identified and located and suitable means, e.g., a bioabsorbable glue is employed to block these rents.

Distraction of the intervertebral disc space can then be accomplished, as described above. Once under traction, a biomaterial, e.g., biopolymer of the present invention is introduced to the distracted space. The polymer is preferably cured over 3 to 5 minutes, and preferably within 1 to 2 minutes. The arthroscopic cannula and the application cannula are removed. The material is further allowed to harden over 15 to 20 minutes and the disc traction is removed.

The desired quantity of the curable biomaterial is delivered by minimally invasive means to the prepared site. Uncured biomaterial, either in bulk or in the form of separate reactive components, can be stored in suitable storage containers, e.g., sterile, teflon-lined metal canisters. The biomaterial can be delivered, as with a pump, from a storage canister to the delivery cannula on demand. Biomaterial can be delivered in the form of a single composition, or can be delivered in the form of a plurality of components or ingredients. For instance, biomaterial components can be separately stored and suitably mixed or combined either in the course of delivery or at the injury site itself.

In terms of its component parts, a preferred delivery system of the present invention will typically include a motor drive unit, with a remote controller, associated tube sets, a nonscope inflow delivery cannula, having independent fluid dynamics pressure and flow rate adjustments, attachments for the flush, vacuum, waste canister, and overflow jars.

The application cannula is inserted into the joint or disc space and under visualization from the fiberoptic scope the biomaterial is delivered. The flow of the biomaterial is controlled by the operator via a foot pedal connected to the pumping mechanism on the polymer canister. The biomaterial flows from the tip of the application catheter to fill the space provided.

The delivered biomaterial is allowed to cure, or cured by minimally invasive means and in such a manner that the cured biomaterial is retained in apposition to the prepared site. As described herein, the biomaterial can be cured by any suitable means, either in a single step or in stages as it is delivered. Once

cured, the biomaterial surface can be contoured as needed by other suitable, e.g., endoscopic or arthroscopic, instruments. The joint is irrigated and the instruments removed from the portals.

At that point, interoperative x-rays are obtained to substantiate the preservation of the intervertebral disc space. Direct observation of the intervertebral foramina for free cursing of the nerve rootlet is substantiated by visualization. The retracted muscles are replaced and the local fascia is closed with interrupted absorbable suture. The subcutaneous fascia and skin are then closed in the usual fashion. The wound is then dressed.

As mentioned above, the cured biomaterial can be subjected to further physical/chemical modifications, e.g., in order to enhance it performance, biocompatability, biostability, and the like. For instance, calcitonin and inflammatory inhibiting molecules such as Interleuken I inhibitors can be attached to the bone composite surface to prevent local osteoporosis and local inflammatory response which may cause loosening. Similarly, the surface of the cured biomaterial can optionally be modified in order to alter, e.g., reduce, its lubricity or coefficient of friction.

Diarthroidal and Amphiarthroidal Joints.

The method and biomaterials of the present invention can be used for the repair of other tissues and joints as well, including, for instance, the glenoid surface of the shoulder, the first carpometacarpal joint of the hand, the knee, the hip, the hallux joint, the temporal mandibular joint, the subtalar joint in the ankle, the other metatarsal phalangeal joints of the feet.

With respect to the shoulder, for instance, a common situation arises in the elderly patient who has a degenerated rotator cuff. Usually, such patients have lost the superior portion of the rotator cuff with the complete loss of the supraspinatus tendon. Often they also have a superior riding of the humerus so that it articulates very high on the glenoid and with any abduction there is significant impingement on the acromium process.

Using the approach presently described, a biomaterial can be delivered, cured, and attached to the glenoid, all using minimally invasive means, in order to resurface the glenoid surface and extend up over the superior portion of the humerus. There the cured biomaterial will act as a spacer between the humerus and the acromium process. Resurfacing the underside of the acromium and the glenoid with a single structure that allows the humerus to be spaced down from the acromium process and to avoid impingement on the acromium with abduction.

Other areas of the body that will also benefit from the creation of a spacer, yet do not involve significant weight-bearing constraints, include the first carpometacarpal joint of the hand, the radialhumeral joint. The method of the present invention can be used to provide a spacer that will allow motion with a minimum of friction, while also providing desired mechanical stability to the area.

Yet other applications include repair of the first carpometacarpal joint, which is another diarthroidal joint. The carpal bone and the base at the metacarpal are normally covered with articular cartilage. This joint, however, is subject to significant degenerative change over time because of stresses that are placed on it by normal hand motion. These stresses can result in a narrowing of the joint space and eventually a bone-on-bone situation, with marked loss of motion and significant. Such a joint can be repaired by minimally invasive means using the method of the present invention, e.g., by placing an appropriate spacer of biomaterial through the arthroscope and affixing it to one side or the other of the joint.

In such a procedure, two small holes can be drilled into the base of the metacarpal, for instance. Curable biomaterial can then be applied into those anchor points and over the surface of the base of the metacarpal. The final cured biomaterial provides both a cushioning and a spacing function, which will serve to decrease pain and improve motion and function.

Yet another joint that is amenable to repair using the present method is the hallux joint, also known as the metatarsal phalangeal joint. In a condition called hallux rigiditus, the cartilage between the base of the 1st phalanx and the end of

the first metatarsal has degenerated and there are significant bony spurs forming due to the degeneration of the cartilage. As with the first carpometacarpal joint at the wrist, the method of this invention can involve arthroscopically drilling a plurality of small holes in the head of the metatarsal and delivering and curing a biomaterial to produce the needed cushioning and spacing.

Yet other areas of application include the fibrocartilage of the temporal mandibular joint, costochondral junctions, and the acromioclavicular joint. Another application involves the subtalar joint in the ankle. This is a common area for medial subluxation of the ankle in the patient with rheumatoid arthritis who gets stretching and weakening of the tibialis posterior tendon and instability at the medial aspect of the ankle, resulting in persistent ankle pain. A biomaterial and method of the present invention can be used to build up the subtalar joint area in order to realign the ankle and correct the eversion of the foot, thereby obviating the need for an ankle fusion.

The foregoing description is intended to be illustrative of the invention, but is not to be considered as comprehensive or limiting of its scope.

CLAIMS

What is claimed is:

1. A method for repairing a diarthroidal or amphiarthroidal joint, the method comprising the steps of:

a) using minimally invasive means to remove damaged or diseased fibrocartilage from the joint and to provide a mold capable of containing curable biomaterial in a desired position within the joint,

b) providing one or more curable biomaterials to the mold, and

c) curing the biomaterials within the mold in order to provide a replacement for the fibrocartilage.

2. A method according to claim 1 wherein the method is used to repair a diarthroidal joint in the form of an intervertebral disc.

3. A method according to claim 2 wherein the method comprises the steps of:

a) using microsurgical techniques to perform a discectomy while preserving an outer annular shell,

b) providing one or more curable biomaterials to the interior of the annular shell, and

c) curing the biomaterials in order to provide a replacement disc.

4. A method according to claim 3 wherein the discectomy comprises the step of distracting the disc space by means of inflatable distraction means.

5. A method according to claim 4 wherein the distraction means are provided in the form of an inflatable balloon.

6. A method according to claim 5 wherein the balloon is delivered in deflated form to the interior of the annulus and there inflated in order to distract the disc space and provide a mold for the delivery of biomaterial.

7. A method according to claim 6 wherein the balloon is formed of a polymer selected from the group consisting of supported and unsupported polyolefin copolymers, polyethylene, and polyethylene terephthalate.

8. A composition comprising a biomaterial capable of being delivered to the site of cartilage damage and there cured in order to provide a replacement for the cartilage.

9. A composition according to claim 8 wherein the biomaterial is provided in the form of a curable polyurethane.

10. A composition according to claim 8 wherein the polyurethane is capable of being mixed at the time of delivery in order to initiate its cure.

11. An apparatus for use in joint repair, the apparatus comprising an insertable, inflatable balloon being suitably dimensioned to be positioned within the intervertebral disc space of a human and there inflated in order to distract the disc space.

12. An apparatus according to claim 11 wherein the ballon is capable of being inflated with biomaterial in order to distract the disc space.

13. An apparatus according to claim 11 wherein the apparatus comprises rigid walls and is suitably dimensioned to be positioned within the intervertebral disc space of a human and there inflated in order to distract the disc space.

14. An apparatus according to claim 13 wherein the balloon is prepared of a material selected from the group consisting of supported and unsupported polyolefin copolymers, polyethylene, and polyethylene terephthalate.

15. A diarthroidal or amphiarthroidal joint having interposed therein a biomaterial that has been cured *in situ*.

16. A joint according to claim 15 wherein the biomaterial was formed by mixing a two-component polyurethane.

17. An apparatus according to claim 12 wherein the apparatus is provided in the form of an inflatable balloon inflatably attached to the distal end of a delivery shaft.

18. An apparatus according to claim 17 wherein the balloon is comprises a material that permits gasses to be vented from the balloon upon filling with biomaterial.

19. An apparatus according to claim 18 wherein the material comprises a nylon mesh.

20. An apparatus according to claim 17 wherein the balloon is severably attached to the shaft.

21. An apparatus according to claim 12 wherein the balloon is capable of being inflated with biomaterial to provide up to about 10 atmospheres distraction pressure.

22. A method according to claim 4 wherein the inflatable distraction means comprise an inflatable balloon attached to the distal end of a delivery shaft.

23. A method according to claim 22 wherein the balloon comprises a material that permits gasses to be vented from the balloon upon filling with biomaterial.

24. A method according to claim 23 wherein the material comprises a nylon mesh.

25. A joint according to claim 15 wherein the cured biomaterial is contained with an inflated balloon.

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/44

US CL :623/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/86, 92, 94; 623/16-18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 5,549,679 A (KUSLICH) 27 August 1996, entire document.	1-8, 11-14, 17-24
X	US 4,570,270 A (OECHSLE, III) 18 February 1986, entire document.	8-10
X	US 3,875,595 A (FRONING) 08 April 1975, entire document.	11-14, 17, 20, 21
X	US 4,904,260 A (RAY et al) 27 February 1990, entire document.	11-14, 17, 20, 21
A	US 5,171,280 A (BAUMGARTNER) December 1992, entire document.	1-14, 17-24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

09 APRIL 1997

Date of mailing of the international search report

01 MAY 1997

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